

DOCKET NO.: ALLE0064-110  
(17595 (BOT))  
Serial No. 10/621,054

PATENT

### REMARKS

Claims 1-17 were pending. Claims 1 and 8 have been amended by incorporating the elements of claim 4-5 and 10-11 respectively, and are clearly supported by the specification, the originally filed claims, and Figure 3. Claims 14 and 17 have also been amended, and are clearly supported by Example 1 at page 25 and the original claim 16. Claims 4-5 and 10, 11 and 16 have been canceled without prejudice. Claims 17-21 have been added to specify the device that is used in the described methods. Claims 22-24 have been added to specify the distances between the perforations of the devices claimed. Support for the new claims are clearly supported by the specification, the originally filed claims, and Figure 3. New claims 25 and 26 are support by the specification at, for example, page 23, lines 15-17 and Figure 4. Upon entry of the above amendment, claims 1-3, 6-9, and 12-15, and 17-26 will be pending in this application.

No new matter is added.

#### I. Overview

(a) With regard to the section 102(b) rejections, it is Applicant's belief that the claims are patentable over the references cited because the references do not teach or even suggest a device that comprises **non-overlapping** first and second plurality of perforations, wherein the uniform spacing of the first and second plurality of perforations are different.

Figure 3 of the present application shows an example of a non-overlapping set of first and second plurality of perforations, **as none of the perforation of the first set of plurality of perforations is part of the second set** (Exhibit 1). On the other hand, the Figures in Gardiner shows an overlapping of the first and second set. For example,

Figure 4 of Gardiner shows that perforation number 16 is part of both the horizontal set of perforations and the vertical set (Exhibit 2).

(b) With regard to the section 103(a) rejection, it is Applicant's belief that the claims are patentable over the references cited because there is no motivation to combine the cited references. There would be no motivation to combine the references because, for example, the Walker relates to the treatment of hyperhidrosis and Gardiner relates to the treatment of diabetes—and **hyperhidrosis and diabetes are very different medical conditions** such that techniques of treatment of one would not be applicable to the other.

Also, even if Walker and Gardiner were combined, the combination would not result in the claimed invention which, for example, requires

- (i) **injection through more than one perforation per injection session, and**
- (ii) **marking of the injection sites.**

## II. The Claims are Novel

### Gardiner

Claims 1-5 and 8-11 are rejected under 35 U.S.C § 102(b) as being anticipated by Gardiner (U.S. Patent 4,228,796). For clarity, Applicant has amended the claims to recite the "non-overlapping" set of perforations feature of the invention. Further, Applicant respectfully asserts that Gardiner does not anticipate the claimed invention because Gardiner does not teach or even suggest a device for assisting hyperhidrosis therapy as described in claims 1 and 8 including wherein the device comprises non-overlapping first and second plurality of perforations, wherein the uniform spacing of the first and second plurality of perforations are different. Figure 3 of the present application shows an example of a non-overlapping set of first and second plurality of perforations, **as none of**

**the perforation of the first set of plurality of perforations is part of the second set (Exhibit 1).**

The devices described in Gardiner do not contain two non-overlapping pluralities of perforations that are separated by different uniform distances. For example, Figure 4 of Gardiner shows that perforation number 16 is part of both the horizontal set of perforations and the vertical set (Exhibit 2). The perforations that are separated by different distances are distinct perforations, and cannot be grouped together with another group of perforations as the Office has done for Gardiner.

Therefore, Gardiner does not teach or suggest having two sets of perforations that are separated by two different uniform distances. Gardiner also does not teach or even suggest a device where the distance between the perforations is about 0.1 to about 4.0 cm.

Accordingly, because Gardiner does not teach each and every element of the pending claims Gardiner does not anticipate the claimed invention. Thus, the claims are patentable over Gardiner, and Applicant respectfully requests the that Office to withdraw the rejection under 102(b).

#### **Whitmore**

Claims 1-2, 4-8, and 10-13 are rejected under 35 U.S.C § 102(b) as being anticipated by Whitmore (U.S. Patent 6,036,632). Applicant respectfully asserts that Whitmore, like Gardiner, does not anticipate the claimed invention because the Whitmore patent does not teach or even suggest a device comprising a non-overlapping first and second plurality of perforations, wherein the uniform spacing of the first and second plurality of perforations are different. Please see above discussion for patentability of the claimed invention over Gardiner.

Thus, like Gardiner, the Whitmore patent does not teach each and every element of the pending claims, and therefore the Whitmore patent does not anticipate the claimed invention. Accordingly, Applicant respectfully requests the Office to withdraw the rejection under 102(b).

### III. The Claims Are Not Obvious

Claims 14-17 are rejected under 35 U.S.C § 103(a) as being obvious over Walker (US 2002/0085036) in view of Gardiner (US 4,228,796). Applicant respectfully disagrees.

The claims are not obvious over Walker and Gardiner because there is no motivation to combine references to arrive at the claimed invention. Further, even if the cited reference were combined, the combination of the references does not result in the claimed invention. For example, claim 14 recites (emphasis added):

A method for assisting a **hyperhydrosis** therapy, the method comprising...(c) extending a **marker** through a perforation so as to mark a dermal surface under the lower face of the material...(e) administering a botulinum toxin to **more than one marked dermal** surface per each administration session.

#### **Insulin Is Different From Diabetes**

Gardiner teaches the use of a device with perforations for injecting insulin to treat diabetes. However, Gardiner does not teach or suggest the use of the device for administering a botulinum toxin for treating a hyperhidrosis. One of ordinary skill would not be motivated to use the device of Gardiner for administering a botulinum toxin for treating hyperhidrosis because diabetes and hyperhidrosis are entirely different

medical conditions. For example, techniques for treating a hyperhidrosis would not be applicable to the treatment of insulin, and vice versa.

### **Injection Through More Than One Perforation Per Injection Session**

Even if Walker and Gardiner were combined, the combination of the references would not result in the claimed invention. For example, the claimed invention recites that a botulinum toxin is administered to more than one marked dermal surface per each administration session. On the contrary, Gardiner teaches the administration of one shot of insulin through one perforation per injection session. For example, the perforations of Gardiner are marked "MON" through "SUN" for one injection to each perforation per each injection session, i.e., one injection per each day of the week (see Figure 5 of Gardiner). Thus, even if one of ordinary skill were motivated to combine Gardiner and Walker, the resulting method would be a method of injecting one shot of botulinum toxin through one perforation per each injection session, i.e., one shot of botulinum toxin injection per day. Clearly, such method is not the claimed invention. The claimed invention requires the administration of botulinum toxin through **more than one** perforation per administration session.

### **Marking the Dermal Surface**

Further, the combination of Walker and Gardiner would not result in the claimed invention because the claimed invention recites a step of marking the dermal surface through the perforation (see Claim 14). There is nothing in the Walker reference or in Gardiner that discloses the marking of the dermal surface through the perforation. The Gardiner reference describes insulin injection guides that one of skill in the art would strap to one's body and then inject through the guide. The Gardiner reference never describes marking the dermal surface and then removing the guide.

For example, Gardiner states in the “Summary of Invention” section “[t]he user can then inject himself through the hole.” (Gardiner, Col. 1, lines 50-51). Gardiner also states, “After the guide 10 is placed on the leg, the proper hole is selected and the user administers an injection to his thigh *through* the selected hole.” (Gardiner, Col. 10, lines 2-4). The Gardiner reference never refers to making marks through the guide, then removing the guide.

According to the Office, “Gardiner teaches the use of a device ...to assist in marking a dermal area to be given multiple injections as disclosed in column [sic] 40-43. The device allows the user to mark areas that need to be injected and identify areas that have already been injected, as disclosed in column 1, lines 29-39.” (Office Action, page 4). Applicant respectfully disagrees with the characterization of the Gardiner reference.

As an initial point, it is unclear as to what column the Office is referring to when it refers to columns “40-43” as there are only 4 columns in the entire Gardiner patent. However, even without a specific citation, Applicant is unable to identify a section of Gardiner that describes marking the dermal area. The Gardiner reference only discloses making injections “through the hole” in the guide (See above). The Gardiner reference does not teach or even suggest marking the whole, then removing the guide. (Claim 14). Additionally, there is nothing in Gardiner that suggests marking the dermal surface through the perforation, removing the device, then making the injection (Claim 17). Gardiner at most discloses making the injection through the device, which is not claimed in the pending claims.

There is nothing in the Walker reference that would correct the deficiency of Gardiner. Accordingly, even if combined the references do not contain all the elements of the claimed inventions and produce the claimed invention.

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With respect to claims 18-21, Gardiner does not teach or even suggest a device as described in claims 1 and 8, of from which the new claims depend. Neither references either alone or in combination suggest modifying the devices described in Gardiner such that the device would be the same as described in amended claims 1 and 8. Accordingly, the references either alone or in combination do not produce the claimed invention.

Accordingly, because Walker either alone in combination with Gardiner does not yield the claimed invention the pending claims are not obvious. Thus, the claims are patentable over Walker in view of Gardiner, and Applicant respectfully requests the Office to withdraw the rejection under 103(a).

In view of the foregoing, Applicant submits that the pending claims are in condition for allowance, and an early Office Action to that effect is earnestly solicited.

Respectfully submitted,

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Quan L. Nguyen  
Registration No. 46,957

**COZEN O'CONNOR**  
1900 Market St.  
Philadelphia, PA 19103  
(215) 665-2158 (Telephone)  
(215) 701-2057 (Facsimile)

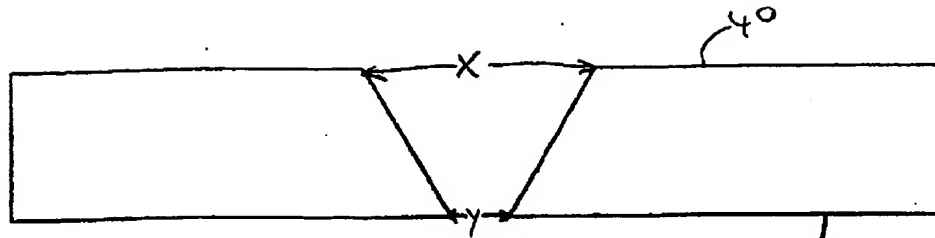


Figure 4

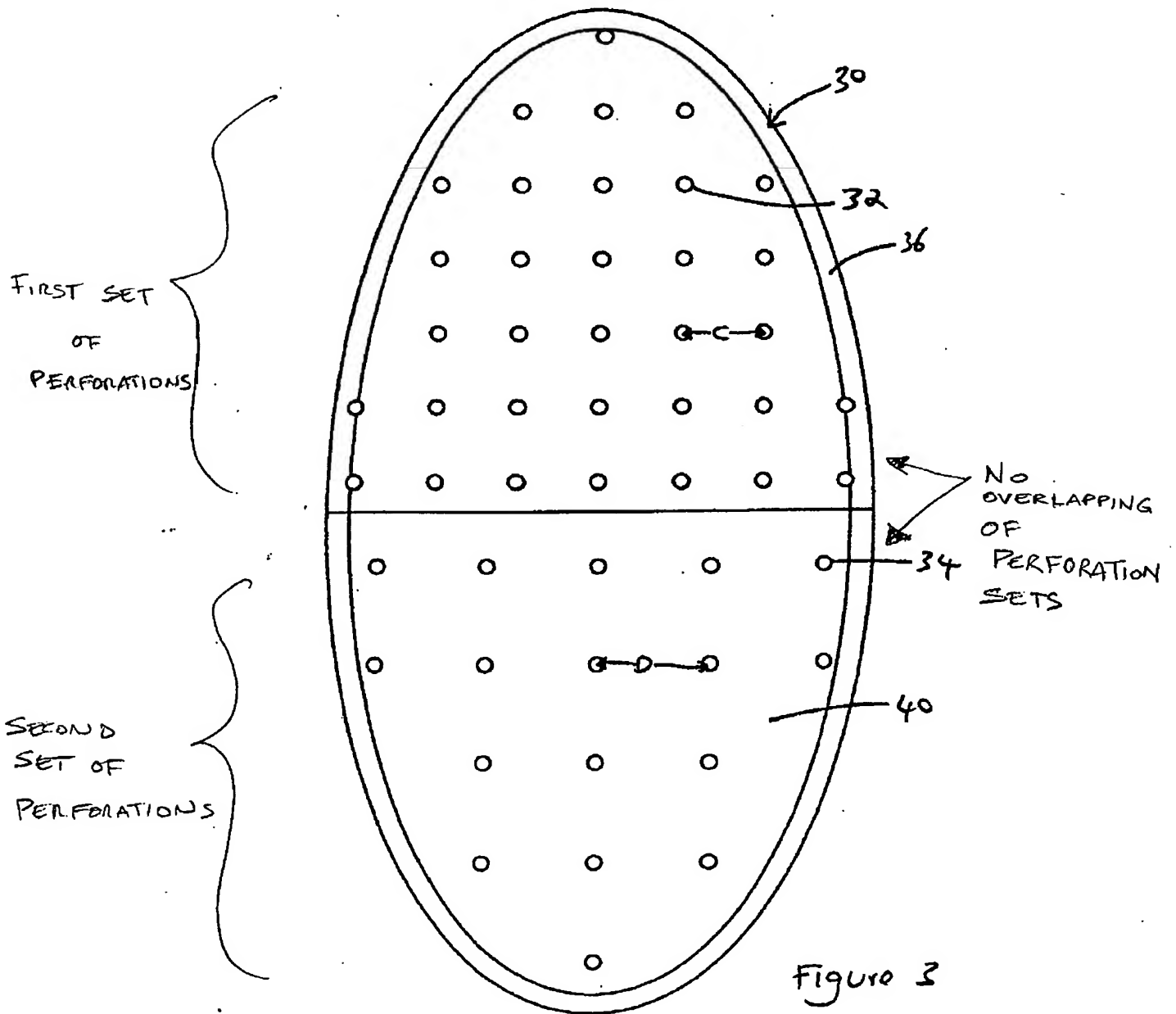


Figure 3



U.S. Patent

Oct. 21, 1980

4,228,796

Fig. 1

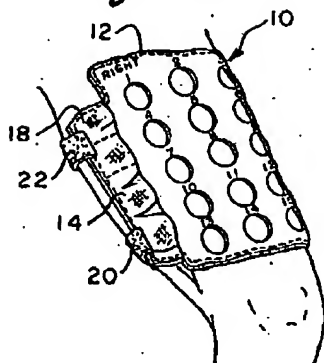


Fig. 2

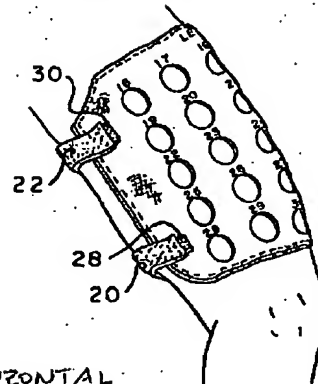
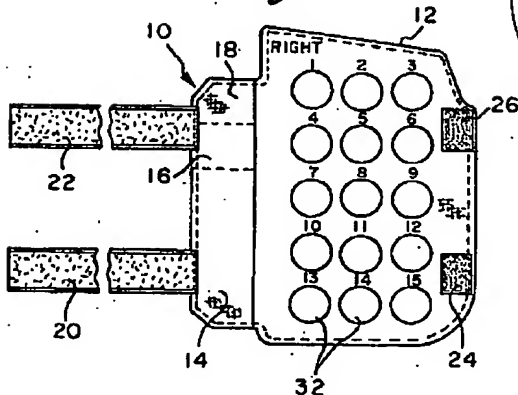


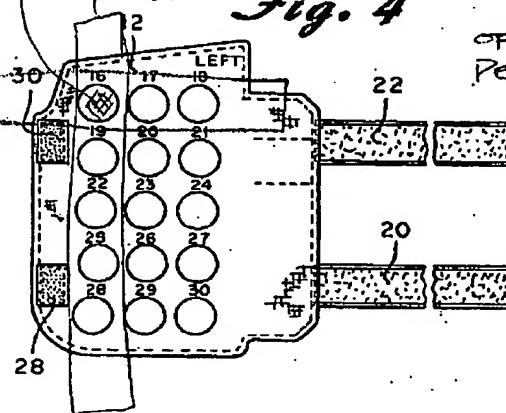
Fig. 3



HORIZONTAL SET

VERTICAL SET

Fig. 4



OVERLAPPING OF THE TWO SETS OF PERFORATIONS

Fig. 5

